

## § 886.1630

premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[55 FR 48442, Nov. 20, 1990, as amended at 66 FR 38811, July 25, 2001]

### § 886.1630 AC-powered photostimulator.

(a) *Identification.* An AC-powered photostimulator is an AC-powered device intended to provide light stimulus which allows measurement of retinal or visual function by perceptual or electrical methods (e.g., stroboscope).

(b) *Classification.* Class II.

### § 886.1640 Ophthalmic preamplifier.

(a) *Identification.* An ophthalmic preamplifier is an AC-powered or battery-powered device intended to amplify electrical signals from the eye in electroretinography (recording retinal action currents from the surface of the eyeball after stimulation by light), electrooculography (testing for retinal dysfunction by comparing the standing potential in the front and the back of the eyeball), and electromyography (recording electrical currents generated in active muscle).

(b) *Classification.* Class II.

### § 886.1650 Ophthalmic bar prism.

(a) *Identification.* An ophthalmic bar prism is a device that is a bar composed of fused prisms of gradually increasing strengths intended to measure latent and manifest strabismus (eye muscle deviation) or the power of fusion of a patient's eyes.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning

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records, and § 820.198, with respect to complaint files.

[52 FR 33355, Sept. 2, 1987, as amended at 53 FR 35605, Sept. 14, 1988; 66 FR 38812, July 25, 2001]

### § 886.1655 Ophthalmic Fresnel prism.

(a) *Identification.* An ophthalmic Fresnel prism is a device that is a thin plastic sheet with embossed rulings which provides the optical effect of a prism. The device is intended to be applied to spectacle lenses to give a prismatic effect.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[52 FR 33355, Sept. 2, 1987, as amended at 53 FR 35605, Sept. 14, 1988; 66 FR 38812, July 25, 2001]

### § 886.1660 Gonioscopic prism.

(a) *Identification.* A gonioscopic prism is a device that is a prism intended to be placed on the eye to study the anterior chamber. The device may have angled mirrors to facilitate visualization of anatomical features.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

[52 FR 33355, Sept. 2, 1987, as amended at 53 FR 35605, Sept. 14, 1988; 59 FR 63013, Dec. 7, 1994; 66 FR 38812, July 25, 2001]

### § 886.1665 Ophthalmic rotary prism.

(a) *Identification.* An ophthalmic rotary prism is a device with various prismatic powers intended to be handheld and used to measure ocular deviation in patients with latent or manifest strabismus (eye muscle deviation).

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter,

subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[52 FR 33355, Sept. 2, 1987, as amended at 53 FR 35605, Sept. 14, 1988; 66 FR 38812, July 25, 2001]

#### § 886.1670 Ophthalmic isotope uptake probe.

(a) *Identification.* An ophthalmic isotope uptake probe is an AC-powered device intended to measure, by a probe which is placed in close proximity to the eye, the uptake of a radioisotope (phosphorus 32) by tumors to detect tumor masses on, around, or within the eye.

(b) *Classification.* Class II.

#### § 886.1680 Ophthalmic projector.

(a) *Identification.* An ophthalmic projector is an AC-powered device intended to project an image on a screen for vision testing.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

[55 FR 48442, Nov. 20, 1990, as amended at 59 FR 63013, Dec. 7, 1994; 66 FR 38812, July 25, 2001]

#### § 886.1690 Pupillograph.

(a) *Identification.* A pupillograph is an AC-powered device intended to measure the pupil of the eye by reflected light and record the responses of the pupil.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

[55 FR 48442, Nov. 20, 1990, as amended at 59 FR 63013, Dec. 7, 1994; 66 FR 38812, July 25, 2001]

#### § 886.1700 Pupillometer.

(a) *Identification.* A pupillometer is an AC-powered or manual device intended to measure by reflected light the width or diameter of the pupil of the eye.

(b) *Classification.* Class I (general controls). The AC-powered device and the manual device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The manual device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[55 FR 48442, Nov. 20, 1990, as amended at 59 FR 63013, Dec. 7, 1994; 66 FR 38812, July 25, 2001]

#### § 886.1750 Skiascopic rack.

(a) *Identification.* A skiascopic rack is a device that is a rack and a set of attached ophthalmic lenses of various dioptric strengths intended as an aid in refraction.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

[52 FR 33355, Sept. 2, 1987, as amended at 61 FR 1124, Jan. 16, 1996; 66 FR 38812, July 25, 2001]

#### § 886.1760 Ophthalmic refractometer.

(a) *Identification.* An ophthalmic refractometer is an automatic AC-powered device that consists of a fixation system, a measurement and recording system, and an alignment system intended to measure the refractive power of the eye by measuring light reflexes from the retina.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9.

[52 FR 33355, Sept. 2, 1987, as amended at 61 FR 1124, Jan. 16, 1996; 66 FR 38812, July 25, 2001]

#### § 886.1770 Manual refractor.

(a) *Identification.* A manual refractor is a device that is a set of lenses of various dioptric powers intended to measure the refractive error of the eye.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in